

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): **Luca GIANNI, Maurizio D'INCALCI, Filippo DE BRAUD, Silvia MARSONI, José María JIMENO DOÑAQUE, and Luis LOPEZ LAZARO**  
Group Art Unit: **TBA**

Serial No.: **TBA** Examiner: **TBA**

Filed: **HEREWITH**

For: **COMBINATION THERAPY COMPRISING THE USE OF ET-743 AND DOXORUBICIN FOR TREATING CANCER**

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R.

§§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, are made of record to assist the Patent and Trademark Office in its examination of this application.

The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or

submitted to the Patent and Trademark Office in application Serial No. \_\_\_\_\_, filed  
\_\_\_\_\_.


**IAP9 Rec'd PCT/PTO 12 MAY 2006**

4. ☒ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
- ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of a national application other than a CPA; or
  - ☒ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or
  - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits; or
  - ☐ 37 C.F.R. §1.97(b)(4), before the mailing date of a first office action after the filing of an RCE under §1.114.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 13-4500, Order No. 4126-4040.

Respectfully submitted,  
MORGAN & FINNEGAN, L.L.P.

Dated: May 12, 2006

By:

  
Kenneth H. Sonnenfeld // Michael A. Willis  
Reg. No. 33,285 // Reg. No. 53,913

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<b>FORM PTO-1449A</b>  <b>INFORMATION DISCLOSURE CITATION</b>	Attorney Docket: 4126-4040	Serial No. TBA <b>10/579251</b>
	Applicant: Luca GIANNI, Maurizio D'INCALCI, Filippo DE BRAUD, Silvia MARSONI, José María JIMENO DOÑAQUE, and Luis LOPEZ LAZARO	
	Filing Date: Herewith	Group Art Unit: TBA

## U.S. PATENT / PUBLICATION DOCUMENTS

Examiner Initial	Patent/Publication Number	Publication/Issue Date	Name	Filing Date

## FOREIGN PATENT DOCUMENTS

Examiner Initial	Patent Number	Publication Date	Country	Copy Filed	Translation
	1. WO 00/69441	Nov. 23, 2000	WO	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Abstract <input checked="" type="checkbox"/> N/A
	2. WO 02/36135 A2	May 10, 2002	WO	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Abstract <input checked="" type="checkbox"/> N/A
	3. WO 03/039571 A1	May 15, 2003	WO	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Abstract <input checked="" type="checkbox"/> N/A
	4.			<input type="checkbox"/> Yes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Abstract <input type="checkbox"/> N/A
	5.			<input type="checkbox"/> Yes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Abstract <input type="checkbox"/> N/A
	6.			<input type="checkbox"/> Yes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Abstract <input type="checkbox"/> N/A
	7.			<input type="checkbox"/> Yes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Abstract <input type="checkbox"/> N/A
	8.			<input type="checkbox"/> Yes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Abstract <input type="checkbox"/> N/A

Examiner	Date Considered
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

<b>FORM PTO-1449B</b>  <b>INFORMATION DISCLOSURE</b> <b>CITATION</b>		Attorney Docket: 4126-4040	Serial No.: TBA
		Applicant: Luca GIANNI, Maurizio D'INCALCI, Filippo DE BRAUD, Silvia MARSONI, José María JIMENO DONAQUE, and Luis LOPEZ LAZARO	
		Filing Date: Herewith	Group Art Unit: TBA
<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
	1.	Naoto TAKAHASHI et al. "Sequence-Dependent Enhancement of Cytotoxicity Produced by Ecteinascidin 743 (ET-743) with Doxorubicin or Paclitaxel in Soft Tissue Sarcoma Cells," <u>Clinical Cancer Research</u> , Vol. 7, No. 10, pgs. 3251-3257 (October 2001).	
	2.	Charlotte VAN KESTEREN et al. "Clinical Pharmacology of the Novel Marine-derived Anticancer Agent Ecteinascidin 743 Administered as a 1- and 3-h Infusion in a Phase I Study," <u>Anti-Cancer Drugs</u> , Vol. 13, No. 4, pgs. 381-393, (April 2002).	
	3.	Charlotte VAN KESTEREN et al. "Yondelis® (trabectedin. ET-743): The Development of an Anticancer Agent of Marine Origin" <u>Anti-Cancer Drugs</u> , Vol. 14, No. 7, pgs. 487-502, (August 2003).	
	4.	Caroline LAVERDIERE et al. "Phase II Study of Ecteinascidin 743 in Heavily Pretreated with Recurrent Osteosarcoma," <u>American Cancer Society</u> , Vol. 98, No. 4, pgs. 832-840 (published on-line June 12, 2003).	
	5.	L. GIANNI et al. "Definition of the Least Toxic Sequence and Optimal Therapeutic Dose of Yondelis® in Combination with Doxorubicin in Patients with Untreated Metastatic Soft Tissue Sarcomas and Advanced Pre-Treated Anthracycline," <u>Clinical Cancer Research</u> , Vol. 9, No. 16, pg. 6081S (December 2003).	
	6.		
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Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*